

1 JEFFREY B. COOPERSMITH (SBN 252819)
2 AMY WALSH (Admitted Pro Hac Vice)
3 STEPHEN A. CAZARES (SBN 201864)
4 ORRICK, HERRINGTON & SUTCLIFFE LLP
5 The Orrick Building
6 405 Howard Street
7 San Francisco, CA 94105-2669
8 Telephone: (415) 773-5700
9 Facsimile: (415) 773-5759

10 Email: jcoopersmith@orrick.com; awalsh@orrick.com;
11 scazares@orrick.com

12 Attorneys for Defendant
13 RAMESH "SUNNY" BALWANI

14 UNITED STATES DISTRICT COURT
15 NORTHERN DISTRICT OF CALIFORNIA
16 SAN JOSE DIVISION

17 UNITED STATES OF AMERICA,
18 Plaintiff,
19 v.
20 RAMESH "SUNNY" BALWANI,
21 Defendant.

Case No. CR-18-00258-EJD

**MOTION TO EXCLUDE EVIDENCE
AND ARGUMENT THAT
PHARMACEUTICAL REPORTS WERE
IMPROPERLY ALTERED**

**Date: March 14, 2022
Time: 9:00 a.m.
CTRM.: 4, 5th Floor**

Hon. Edward J. Davila

**NOTICE OF MOTION AND MOTION TO EXCLUDE EVIDENCE AND ARGUMENT
THAT PHARMACEUTICAL REPORTS WERE IMPROPERLY ALTERED**

PLEASE TAKE NOTICE that on March 14, 2022, at 9:00 a.m., or on such other date and time as the Court may order, in Courtroom 4 of the above-captioned Court, located at 280 South First Street, San Jose, CA 95113, before the Honorable Edward J. Davila, Defendant Ramesh “Sunny” Balwani will and hereby does move the Court to exclude evidence and argument that pharmaceutical reports were improperly altered, whether through the admission of exhibits or testimony or through statements in opening or argument at closing. The Motion is based on the below Memorandum of Points and Authorities, the concurrently filed Declaration of Amy Walsh, the record in this case, and any other matters that the Court deems appropriate.

DATED: February 28, 2022

Respectfully submitted,

ORRICK HERRINGTON & SUTCLIFFE LLP

By: /s/ Jeffrey B. Coopersmith
Jeffrey B. Coopersmith

Attorney for Defendant
RAMESH “SUNNY” BALWANI

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

At a meet and confer conference on February 17, 2022, the government informed undersigned counsel that it intends to offer evidence of alleged improper alteration of certain pharmaceutical reports, including the unauthorized addition of pharmaceutical company logos. Declaration of Amy Walsh ¶ 3.¹ Mr. Balwani was unconnected to these actions, and the Court should exclude the government's evidence, as well as preclude the government from referencing such evidence in its opening statement or raising it in closing arguments.

The only conceivable theory the government could use to offer against Mr. Balwani evidence of altering of pharmaceutical reports is vicarious liability, such as conspiracy or co-schemer liability. *See United States v. Lothian*, 976 F.2d 1257, 1262–63 (9th Cir. 1992). The reason this theory fails is that the government cannot show that Mr. Balwani was participating in a conspiracy or scheme to defraud when the reports were altered by Elizabeth Holmes or others at Theranos unbeknownst to Mr. Balwani. Unless the government makes this showing at a Rule 104(b) hearing, the Court should exclude any evidence or argument that pharmaceutical reports were improperly altered. *See Fed. R. Evid. 104(b)*.

Even if the government could prove the elements needed to admit this evidence, the evidence should be excluded under Rule 403. *See Fed. R. Evid. 403*. The sole witness who explained how pharmaceutical logos were placed on reports was Elizabeth Holmes, who confirmed on the witness stand that *she* was the one who altered the reports. Unless the government announces that it is calling Ms. Holmes as a witness, allowing it to present evidence in Mr. Balwani's case that the reports were altered creates a high risk that the jury will think Mr. Balwani altered the reports. Leaving the jury with such a powerful misimpression would undermine the truth-seeking function of the trial and should not be permitted.

¹ On February 28, 2022, the government indicated that the witnesses who testified on this issue in the Holmes trial would be called in the first half of the government's case-in-chief against Mr. Balwani.

II. FACTUAL BACKGROUND

Before Mr. Balwani joined Theranos, the company partnered with GlaxoSmithKline (GSK), Pfizer, and Schering-Plough to conduct studies using Theranos' technology. Three reports resulted from this work: (1) Theranos' Angiogenesis Study Report resulting from its work with Pfizer ("Pfizer report"), (2) Theranos' Assay Development Report resulting from its work with Schering-Plough ("Schering-Plough report"), and (3) Excerpts from GSK's Metabolic Study Report ("GSK report"). Ex. 2.² These reports were later shared with retail partners and Theranos investors.

During the Holmes trial, the government repeatedly argued that Ms. Holmes improperly altered these reports by adding the Pfizer, Schering-Plough, and GSK logos without the companies' permission and adjusting or omitting some findings in the Schering-Plough and GSK reports. When Ms. Holmes took the stand, she testified that she did in fact add the logos and alter those findings before sending the reports to Walgreens. Ex. 1 (11/23/21 Tr. 7478–79; 11/30/21 Tr. 8154, 8157–60). The government argued that Ms. Holmes made these alterations to mislead investors into thinking that the pharmaceutical companies authored all the reports and comprehensively validated Theranos' technology. Critically, however, no evidence connects Mr. Balwani to these actions, as none exists.

A. The Government's Case Against Ms. Holmes

In its opening statement in the Holmes trial, the government told the jury that Ms. Holmes "misled investors into believing that pharmaceutical companies endorsed and approved the miniature blood analyzer." Ex. 1 (9/8/21 Tr. 542). It used the Pfizer report as an example. Prosecutors showed the jury two versions of the Pfizer Report: one version that Theranos sent to Pfizer at the close of its study, and another version that Theranos sent to potential retail partners and investors. Ex. 1 (9/8/21 Tr. at 543). The first version included only Theranos' logo, but the second version also included Pfizer's logo. *Id.* According to the government, Ms. Holmes "held

² Unless otherwise noted, exhibits cited are attached to the Declaration of Amy Walsh.

1 this [second report] out as demonstrating that Pfizer concluded that the analyzer had superior
 2 performance, good correlations, and robust functionality,” when really “Pfizer did not write this,”
 3 “did not put its logo on,” “did not give its permission to put its logo on,” and “did not make the
 4 conclusions in this report.” Ex. 1 (9/8/21 Tr. 543–544).

5 During its case-in-chief, the government called two pharmaceutical witnesses to testify on
 6 logos: a former Pfizer employee, Shane Weber, and a former Schering-Plough employee,
 7 Constance Cullen.³ While questioning Mr. Weber, the government introduced an October 2008
 8 email from Ms. Holmes to Pfizer, attaching the Pfizer report with only Theranos’ logo. Ex. 1
 9 (10/22/21 Tr. 4362–4365); Ex. 3. The government then displayed the second version of the Pfizer
 10 report with Pfizer’s logo added. Ex.2 at 8. It established elsewhere during the trial that
 11 Ms. Holmes emailed this second version of the Pfizer report, along with reports about work with
 12 Schering-Plough and GSK, to potential investors and described them as “independent due
 13 diligence reports on Theranos systems” and “exemplary reports from pharmaceutical partners.”
 14 Ex. 1 (10/12/21 Tr. 3186–3187) (Miquelon testimony); Ex. 2 at 1; Ex. 1 (10/26/21 Tr. 4681)
 15 (Peterson testimony). Mr. Weber testified that, to his knowledge, Theranos authored the report,
 16 Pfizer did not endorse its conclusions, and Pfizer did not approve the use of its logo. Ex. 1
 17 (10/22/21 Tr. 4397–4402). Using a split screen, the government displayed the two versions of the
 18 report side-by-side so the jury could compare them. The inference was clear: Ms. Holmes added
 19 the Pfizer logo without permission to mislead investors.

20 The government repeated this strategy for Schering-Plough. While questioning
 21 Ms. Cullen, it introduced a December 2009 email from a Theranos employee to Schering-Plough,
 22 attaching the Schering-Plough report with only Theranos’ logo. Ex. 1 (11/02/21 Tr. at 5039–
 23 5041); Ex. 4 at 3. That version of the report included the conclusion that “[t]he Theranos [assay
 24 multiplex] has been shown to give accurate and precise results for three independently calibrated
 25 cartridge lots and all the many instruments used.” Ex. 4 at 19. The government then introduced a
 26

27 ³ The government did not call any witnesses from GSK.
 28

1 different version of the Schering-Plough report, which, like the altered Pfizer report, had been
2 sent to Walgreens and potential investors. Ex. 2 at 34. This version included the Schering-Plough
3 logo and altered the above conclusion to read: “The Theranos [assay multiplex] has been shown
4 to give *more accurate* and precise results for three independently calibrated cartridge lots and all
5 the many instruments used *than current ‘gold standard’ reference methods.*” *Id.* at 18. Ms. Cullen
6 testified that to her knowledge Theranos authored the report and Schering-Plough did not endorse
7 its conclusions or approve the use of its logo. Ex. 1 (11/02/21 Tr. 5041–42, 5045–48). Again, the
8 government used a split screen to display the two versions of the report to the jury.

9 Ms. Holmes was asked on the stand who added the logos to the Pfizer, Schering-Plough,
10 and GSK reports. She responded, “I did.” Ex. 1 (11/23/21 Tr. 7477–78). When asked when she
11 did that, she said, “just before sending them to Walgreens [on April 14, 2010].” Ex. 1 (11/23/21
12 Tr. 7478). Ms. Holmes also testified that she enhanced the conclusion in the Schering-Plough
13 report. Ex. 1 (11/30/21 Tr. 8154 (Question: “Did you add those words [to the conclusion in the
14 Schering-Plough Report]?” Answer: “I think so.”)). As for the GSK report, Ms. Holmes could not
15 remember whether she made any alterations, but she assumed that she added the GSK logo, and
16 she acknowledged that one finding was not in the version of the report sent to Walgreens: “Finger
17 prick/blood draw procedure was difficult (needed larger lancet and better syringe system).” Ex. 1
18 (11/30/21 Tr. 8157–60). Ms. Holmes explained that she added the logos “because the work was
19 done in partnership with those companies” and that she did not intend to convey any
20 misimpression. Ex. 1 (11/23/21 Tr. 7478–79). The change to the conclusion of the Schering-
21 Plough report, so Ms. Holmes testified, “accurately reflect[ed] the data in the document.” Ex. 1
22 (11/30/21 Tr. 8155).

23 In closing, the government reiterated that Ms. Holmes altered the pharmaceutical reports.
24 It again used a split screen to display the Pfizer and Schering-Plough reports both with and
25 without their logos added. Ex. 1 (12/16/21 Tr. 8989). According to the government, the altered
26 reports showed that Ms. Holmes “wants Walgreens, and ... [investors], to conclude that they are
27 independent due diligence reports, that the pharma companies prepared the reports after their own
28 technical validation.” *Id.* 8990.

1 This evidence was critical to the jury's decision to convict Ms. Holmes on four counts of
 2 wire fraud. According to reporting, jurors considered Ms. Holmes' apparent doctoring of the
 3 Pfizer report a "smoking gun."⁴

4
 5 **B. Mr. Balwani Played No Role in Adding Logos or Otherwise Altering
 6 Pharmaceutical Reports**

7 None of the evidence introduced at the Holmes trial suggests that Mr. Balwani knew the
 8 reports shared with investors had been altered without the pharmaceutical companies' permission,
 9 as the government alleged during the Holmes trial. Mr. Balwani was not working for Theranos in
 10 October 2008, when Ms. Holmes emailed the Pfizer report to Pfizer without the Pfizer logo
 11 affixed. Ex. 3. Indeed, Mr. Balwani was not involved in Theranos' relationships with the
 12 pharmaceutical companies generally, other than occasionally being copied on emails from
 13 Ms. Holmes.

14 Mr. Balwani joined Theranos in September 2009, later becoming President and COO of
 15 the company. Before joining, he did his own due diligence on the company. As part of that
 16 process, in August 2009 the company emailed Mr. Balwani a report stating that "Theranos'
 17 technology has been *robustly validated* over the last four years," and that Theranos' clients
 18 "include AstraZeneca, BMS, Celgene, GSK, J&J Centocor, Mayo Clinic, Merck [which acquired
 19 Schering-Plough], Pfizer, and others." Ex. 5 at 1 (emphases added); Ex. 6.

20 And a few months after he joined, Mr. Balwani was copied on an email from Ms. Holmes
 21 to GSK with the GSK report attached *in the same form* later shared with investors, including the
 22 affixed GSK logo. Ex. 7 at 40.

23 And while Mr. Balwani did work for Theranos in December 2009, when the Schering-
 24 Plough Report was emailed to that company without the Schering-Plough logo affixed,

25
 26
 27 ⁴ Sara Randazzo & Meghan Bobrowsky, *Jury in Elizabeth Holmes Trial Seized on Two 'Smoking
 28 Guns' to Convict Theranos Founder, Juror Says*, WALL ST. J. (Jan. 6, 2022),
<https://www.wsj.com/articles/jury-in-elizabeth-holmes-trial-seized-on-two-smoking-guns-to-convict-theranos-founder-juror-says-11641503502>.

1 Mr. Balwani was not copied. Ex. 4.⁵

2 Although Mr. Balwani was involved in Theranos' communications with Walgreens in
3 spring 2010—and was copied on the April 14, 2010, email containing the pharmaceutical reports
4 that Ms. Holmes edited just before sending—nothing suggests that he knew those reports had
5 been altered or were not approved by the pharmaceutical companies.

6 Mr. Balwani is not tied to any of the evidence from the Holmes trial related to the altering
7 of the pharmaceutical reports. Nor is there evidence that Mr. Balwani was involved in a scheme
8 or conspiracy when the reports were altered.

9 10 **III. ARGUMENT**

11 **A. Evidence that Pharmaceutical Companies' Logos Were Added Without** 12 **Permission Should Not Be Admitted Against Mr. Balwani**

13 This Court should exclude any evidence or argument that the pharmaceutical reports were
14 improperly altered unless the government establishes that he can be held vicariously liable for
15 Ms. Holmes's actions when the reports were altered (March–April 2010). “It is well settled that
16 ‘guilt’ is an ‘individual and personal’ matter,” and thus vicarious liability is only permissible in
17 “limited circumstances, such as conspiracy,” *United States v. Holmes*, Case No. 5:18-cr-00258-
18 EJD-1, 2021 WL 2044470, at *37 (N.D. Cal. May 22, 2021) (citation omitted), or where two or
19 more people engage in scheme to defraud, *Lothian*, 976 F.2d at 1262–63 (9th Cir. 1992). It is just
20 as well settled that mere association cannot establish vicarious liability. *See United States v.*
21 *Dunn*, 640 F.2d 987, 989 (9th Cir. 1981). Nor is it enough to act in a way that furthers some
22 objective of a fraudulent scheme or conspiracy even with knowledge of the unlawful plan. *See*
23 *United States v. Reed*, 575 F.3d 900, 927 (9th Cir. 2009). The law aims to “prevent[] the
24 persecution of the innocent for the beliefs and actions of others.” *Bridges v. Wixon*, 326 U.S. 135,

25
26
27 ⁵ A March 19, 2010, email from Ms. Holmes to Walmart, with Mr. Balwani copied, attaches the
28 Schering-Plough report in its original form—i.e., without the Schering-Plough logo or the altered
conclusion. Ex.8. This exhibit was not admitted at the Holmes trial.

1 163 (1945) (Murphy, J., concurring).

2 There is no evidence that Mr. Balwani knew that the logos were added or that the
3 pharmaceutical reports were altered without authorization. The only evidence that could possibly,
4 even if implausibly, suggest otherwise is a March 19, 2010, email from Ms. Holmes to Walmart,
5 copying Mr. Balwani, with the Schering-Plough report attached with only Theranos' logo. *See*
6 Ex.8. Yet nothing suggests that Mr. Balwani knew anything about whether Schering-Plough had
7 given permission to affix its logo or change eight words of text when he later received a copy of
8 Ms. Holmes April 14, 2010, email to Walgreens (Ex. 2). The Schering-Plough report appears at
9 page 34 of Ex. 2, and no evidence suggests that he reviewed the logos on that attachment, let
10 alone that he noticed that *eight* words were different on page 51 of Ex. 2. Being copied on an
11 email with an attachment more than 30 pages in is far too tenuous to support the inference that
12 Mr. Balwani knew the Schering-Plough report, let alone the Pfizer and GSK reports, had been
13 altered without authorization.

14 The only conceivable way the government could tie this evidence to Mr. Balwani is
15 through vicarious liability.⁶ To hold Mr. Balwani liable for the actions of an alleged
16 co-conspirator, the government must prove that he entered into an agreement to intentionally
17 carry out a fraudulent scheme and had the specific intent to defraud. *See, e.g., United States v.*
18 *Freeman*, 498 F.3d 893, 907 (9th Cir. 2007) (conspiracy requires “an agreement to accomplish an
19 illegal objective, ... coupled with one or more acts in furtherance of the illegal purpose, and ...
20 intent necessary to commit the underlying substantive offense”). Only then can Mr. Balwani be
21 held vicariously liable for the reasonably foreseeable actions of co-conspirators made during the
22 course and in furtherance of the conspiracy. *United States v. Chong*, 419 F.3d 1076, 1081 (9th
23 Cir. 2005) (defining *Pinkerton* liability). The same rules apply to co-schemer liability. *Lothian*,
24 976 F.2d at 1262–63 (“a scheme to defraud, ... when more than one person is involved, is

25 _____
26 ⁶ *See Phillips v. United States*, 356 F.2d 297, 303 (9th Cir. 1965) (“[S]o-called ‘constructive’
27 notice or knowledge of a circumstance, based upon the actual knowledge of a co-conspirator ...
28 has no tendency, circumstantially or otherwise, to prove criminal intent.”); *United States v.*
Engelmann, 720 F.3d 1005, 1008 (8th Cir. 2013) (“Fraudulent intent is not presumed or assumed;
it is personal and not imputed. One is chargeable with his own personal intent, not the intent of
some other person.”).

1 analogous to a conspiracy”).

2 Here, however, the government cannot show that Mr. Balwani knowingly entered into any
3 such unlawful agreement when the pharmaceutical reports were altered—on or shortly before
4 April 14, 2010. To the contrary, the documents shared with him before that time conveyed that
5 Theranos’ technology had been “robustly validated” well before he joined the company, Exs. 5–6;
6 that Theranos had successful relationships with multiple pharmaceutical clients, including Pfizer,
7 Merck (which acquired Schering-Plough in 2009), and GSK, *id.*; and that Theranos was sharing
8 reports affixed with pharmaceutical company logos with those very companies, Ex. 7 (email
9 sending GSK report to GSK with company’s logo, and copying Mr. Balwani).

10 Based on Rule 104 and the Due Process clause, the government should not be permitted to
11 introduce evidence that an alleged co-conspirator (or co-schemer) altered the pharmaceutical
12 reports without first showing that a conspiracy or scheme to defraud existed at that time. *See* Fed.
13 R. Evid. 104(b) (“When the relevance of evidence depends on whether a fact exists, proof must
14 be introduced sufficient to support a finding that the fact does exist.”); *Bourjaily v. United States*,
15 483 U.S. 171, 175 (1987) (in the context of Fed. R. Evid. 801(d)(2)(E) “the existence of a
16 conspiracy and [the defendant’s] involvement in it are preliminary questions of fact that, under
17 Rule 401, must be resolved by the court” and shown by a “preponderance of the evidence”). As
18 this Court ruled on an analogous issue in the Holmes trial, the government should proffer in
19 advance—and outside the presence of the jury—the evidence that it believes will connect
20 Mr. Balwani to the altering of the pharmaceutical reports either directly or through vicarious
21 liability. *See Holmes*, 2021 WL 2044470, at *39 (requiring Rule 104 hearing “out of the presence
22 of the jury to consider whether the Government has presented sufficient evidence of a connection
23 to justify admissibility” of evidence that is otherwise unconnected to the defendant). “This
24 approach will insure that the jury will not be tainted by hearing prejudicial evidence—or learning
25 of its existence—until the Government has demonstrated that it will be able to provide an
26 adequate foundation for admission.” *Id.* (internal quotation marks and alterations omitted).

B. Admitting This Evidence Without Explaining Ms. Holmes' Responsibility for Altering the Reports Is Highly Prejudicial and Invites the Jury to Speculate

Even if this evidence could be introduced under a theory of vicarious liability, it should still be excluded under Rule 403 because it would invite the jury to engage in highly prejudicial speculation that Mr. Balwani played a role in altering the reports.

As this Court knows from the Holmes trial, Ms. Holmes personally added the pharmaceutical logos to the Pfizer, Schering-Plough, and GSK reports, and altered language in the Schering-Plough and GSK reports. Ex. 1 (11/23/21 Tr. 7478–79; 11/30/21 Tr. 8154, 8157–60). But the jury in Mr. Balwani's trial will not hear that testimony, which is pure hearsay and would violate Mr. Balwani's Confrontation Clause rights. *See* Fed. R. Evid. 801(c), 802. Instead, Mr. Balwani's jury would hear that pharmaceutical companies received copies of the reports with only Theranos' logo, and that Mr. Balwani was copied on later emails sent to retail partners and investors attaching different versions of the reports—with the pharmaceutical logos added and certain conclusions altered. The implication would be clear but contrary to the truth: that Mr. Balwani altered the reports or at least knew and approved of someone else at Theranos altering them.

The government should not be permitted to introduce misleading evidence that tells only part of the story and impliedly points the finger at Mr. Balwani. This Court plays a crucial role in protecting the truth-seeking function of the trial. Thus, under Rule 403, it may exclude relevant evidence if its “probative value is substantially outweighed by a danger of ... misleading the jury.” Fed. R. Evid. 403. We know how prejudicial this evidence can be given its impact on the jury in the Holmes trial. *See* Randazzo & Bobrowsky, *supra* n.4 (jury viewed alterations to Pfizer report as a “smoking gun”). Evidence that pharmaceutical reports were improperly altered would no doubt invite the jury to speculate that Mr. Balwani was involved. Because the risk of misleading the jury is high, the Court should exclude the evidence under Rule 403.

1 **IV. CONCLUSION**

2 The Court should grant Mr. Balwani's motion and exclude any evidence and argument
3 that the pharmaceutical reports were improperly altered, as well as prohibit the government from
4 mentioning this evidence in its opening statement.
5

6 DATED: February 28, 2022

Respectfully submitted,

7 ORRICK HERRINGTON & SUTCLIFFE LLP
8

9 By: /s/ Jeffrey B. Coopersmith
Jeffrey B. Coopersmith

10 Attorney for Defendant
11 RAMESH "SUNNY" BALWANI
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28